

OPI Pulse: Prescription Drug Abuse and Regulation in Florida

Background:

Beginning in the 1990s, the legal use of medicinal pain relievers by prescription increased dramatically in Florida and throughout the nation. This increase is often attributed to a growing acceptance, at the time, for the use of prescription drugs for the control of chronic pain. While these medications are valuable for the treatment of chronic pain, their use comes with unavoidable risks. Regulators and medical professionals agree that certain controlled substances are highly addictive. Serious complications resulting from the inappropriate use of controlled substances include misuse, abuse, addiction, overdose and death.

Since the mid-1990s, Florida has experienced a steady increase in the prescribing of medicinal pain relievers. Between 1999 and 2002, the sale of pain relievers derived from opium increased 76 percent. This growth in the sale of controlled substances resulted in increased prescription drug abuse and an increase in the number of deaths related to the abuse of prescription medications. In fact, between 1999 and 2002, deaths related to opioids grew by 95 percent. More recently, the Florida Medical Examiners Commission reported that during a six month period in 2010, more than 1,200 Florida deaths were attributed to prescription drugs, which can be translated to about seven deaths a day.

Understanding Prescription Drug Regulation

Federal

The federal Controlled Substances Act of 1970 established a system for classifying and regulating certain prescription drugs such as *opioid analgesics (derived from opium)*. Most state laws are consistent with the federal Controlled Substances Act. Some states also impose additional regulatory requirements above and beyond the federal law. Information on the distribution of controlled substances has been collected by the federal Drug Enforcement Administration (DEA) since 1970 as well. Data collected by the DEA shows a significant increase in the distribution of controlled substances since the mid-1990s. The DEA has verified that between 1997 and 2003, shipments of oxycodone increased 479 percent nationwide. It should be noted that the trend of increased shipments was consistent across the country, regardless of varying state regulations imposed for distributors, prescribers, and dispensers.

Quick Look:

This document includes:

Background Information,
Understanding
Prescription Drug
Regulation, Florida's
Challenges, Quick Facts,
Terms to Understand,
Where to Learn More.

Quick Facts:

- **76:** Percentage of Americans age 60 and over who use two or more prescription drugs
- **37:** Percentage of Americans age 60 and over who use five or more prescription drugs

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Florida

In Florida, Chapter 893 of Florida Statutes sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act. This Act classifies controlled substances into five categories, formally known as *schedules*, based on the characteristics of the drugs in question:

Terms to Understand:

Controlled Substance:

- A drug with potential for abuse and addiction delineated by law in five schedules based on level of risk of addiction and level of medical value.

Dispense:

- The transfer of one or more doses of a medicinal drug by a pharmacist or other licensed practitioner to the ultimate consumer.

Prescribe:

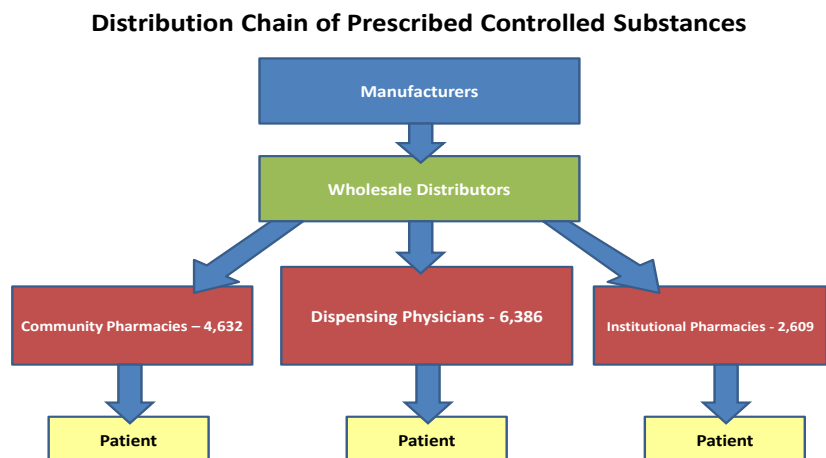
- To order drugs by written and signed forms, or direct verbal communication by a licensed practitioner to another person authorized to dispense.

Administer:

- The direct application of controlled substances whether by injection, inhalation, ingestion, or any other means.

- **Schedule I:** high potential for abuse and no currently accepted medical use; examples include heroin and methaqualone.
- **Schedule II:** high potential for abuse; currently accepted medical use, but severely restricted; abuse may lead to severe psychological or physical dependence; examples include cocaine and morphine.
- **Schedule III:** potential for abuse is less than with drugs in Schedules I and II; currently accepted medical use; however, abuse may lead to moderate or low physical dependence or high psychological dependence. Examples include lysergic acid; ketamine; and some anabolic steroids.
- **Schedule IV:** low potential for abuse relative to the substances in Schedule III; currently accepted medical use, and abuse may lead to limited physical or psychological dependence. Examples include alprazolam; diazepam; and phenobarbital.
- **Schedule V:** low potential for abuse relative to the substances in Schedule IV; currently accepted medical use, and abuse may lead to limited physical or psychological dependence. Examples include low dosage levels of codeine; certain stimulants; and certain narcotic compounds.

In Florida, many parties play a role in the lawful distribution of controlled substances:



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Quick Facts:

- **6,335:** Number of physicians licensed to dispense controlled substances in Florida
- **860:** Current number of registered pain clinics in Florida
- **236:** Number of pain clinics notified by the Department of Health of an intent to revoke registration due to regulatory infraction
- **54:** Number of pain clinics closed in Florida in 2010 as a result of DOH registration revocation
- **72:** Number of pending revocations
- **Manufacturers** develop, produce, and market drugs licensed for use as medication.
- **Distributors** disburse the drugs produced by manufacturers that are licensed for use as medications.
- **Pharmacies** serve as dispensing sites for prescription medications.
- **Physicians or “other practitioners”** are health care providers who practice the profession of medicine. Not all physicians and practitioners choose to dispense prescribed controlled substances within their health care facilities but some do.
- **Pain management clinics** are privately owned facilities or offices which advertise pain treatment and employ a physician who is primarily engaged in the treatment of pain. Not all pain management clinics dispense prescribed controlled substances on site, but some do.

Florida regulates each entity that takes possession of prescription drugs from the manufacturer through various distributors to the dispensing facility or practitioner. Activities involved in the sale and transfer of prescription drugs have been regulated since the early 1980s and these laws have been modified numerous times since then. Distributors are permitted by the Department of Health in accordance with Chapter 499 of the Florida Statutes. Florida law requires prescription drugs to be tracked through a process referred to as pedigree papers. Unlawful possession and transfer of drugs is subject to various criminal penalties. Licensing of health care practitioners is the mechanism for regulating who can prescribe drugs. Practitioners are licensed by specific boards created in law. Dispensing of controlled substances is limited to pharmacists and physicians. Pharmacies and pharmacists are each separately licensed. Pain management clinics are required to register with DOH.

Florida's Challenges:

The Florida House of Representatives Health and Human Services Committee recently conducted a workshop on prescription drug abuse and reviewed the structure and operation of Florida's regulatory programs for prescription medication.

**All data reported by Florida
Department of Health*

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Where to Learn More:

[National Drug Intelligence
Center](#)

[Florida Department of
Law Enforcement](#)

[Centers for Disease
Control Prescription &
Over-the-Counter Drug
Abuse](#)

[Prescription Drug
Monitoring Program in
Florida](#)

[Florida House of
Representatives Health
and Human Services
Committee](#)

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The Committee discussed the challenges facing Florida and officials in attendance considered the following issues:

- The registration of pain clinics depends on the voluntary compliance of the clinic. Regulators are reliant on citizen complaints or clinic advertisement to locate clinics that fail to register.
- It is unknown how many clinics and physician's offices are not known to the registration system.
- When a complaint is received, administrative licensure investigations can be complex, lengthy and yield little proof upon which to take formal action.
- Monitoring controlled substances does not prevent excessive prescribing and dispensing, although some observers assert the process creates a chilling effect.
- Practitioners prescribing and dispensing without valid clinical reasons may choose not to accurately report their activities.
- The sustained and growing presence of prescription drug abuse in Florida constitutes a serious public health threat.

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